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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,084	03/27/2001	Michael A. Evans	19744P001120	2528
20350	7590	06/02/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			ODLAND, KATHRYN P	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/820,084

Applicant(s)

EVANS ET AL.

Examiner

Kathryn Odland

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7, 9, 11-47, 49-94 and 72(renumbered 96) is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8,10,48,71(renumbered 95) and 73(renumbered 97) is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 6, 7, 9, 11-47, 49-94 and 72(renumbered 96) are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated April 8, 2004. Claims 1, 2, 5, 8, 10, 48 and (newly added 71-73) are under consideration. Claims 6, 7, 9, 11-47, and 49-94 are withdrawn from consideration. Claims 3, 4 and 45 are cancelled. In this amendment, applicant adds claims 71-73. However, original claims 71-73 appear in the case as withdrawn. Thus, it is improper to have two sets of claims 71-73. Therefore, these claims have been renumbered as claims 95-97 under 37 CFR rule 126. Moreover, new claim 72, renumbered 96 appears to be drawn to the species of figure 8, a non-elected species, thus, is withdrawn from consideration.

Response to Arguments

1. Applicant's amendments filed April 8, 2004 have been sufficient to overcome the 102(e) rejection over Lary in US 2002/0082592. The rejection has been withdrawn.
2. Applicant's amendments and arguments filed April 8, 2004 have been fully considered but they are not persuasive to overcome the rejection based on Lemelson et al. in US Patent No. 5,728,123.

Applicant has amended claim 1 to include the phrase, "the dissection tool comprising a radially expansive element circumferentially surrounding the catheter body and a cutting surface extending along the radially expansive element, the cutting surface position a distance radially outwardly from the radially expansive element so that the cutting surface traverses the inner layer to the outer layer without penetrating the outer layer upon expansion of the

element.” Applicant argues that Lemelson describes a device where the cutting blades extend generally axially along a portion of the tubular structure rather than circumferentially around the body of the structure. However, applicant has not required that the blade(s) extend circumferentially. Rather applicant claims the expansive element is circumferentially surrounding the catheter and the cutting surface extends along the radially expansive element. This is clearly shown in Lemelson. Further, the cutting surface is clearly positioned at a distance radially outward from the expansive element, as shown in figure 1b.

Applicant also argues that since the Lemelson device is described for use in atherectomy there is no disclosure that the blades cut through the inner layer of the lumen. However, given the expansion via the balloon, the device of Lemelson is capable of penetrating and cutting the inner wall of the lumen **to some degree**. Vessel size and degree of expansion are all factors in determining whether the device will penetrate the lumen. Applicant is reminded that functional language does not hold patentable weight in apparatus claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5, 8,10, and 73 (renumbered 97) are rejected under 35

U.S.C. 102(b) as being anticipated by Lemelson et al. in US Patent No. 5,728,123.

Regarding claim 1, Lemelson et al. disclose a device having a catheter body (9) having a proximal end, a distal end and a lumen therethrough; and a dissection tool (18) disposed near the distal end of the catheter body, as recited in column 2, lines 35-40, column 2, lines 60-65, columns 3 and 4 and seen in figures 1A-1B, for example. Further, the dissection tool of Lemelson et al. has a radially expansive element (11) circumferentially surrounding the catheter body and a cutting surface (via blades 18) extending along the radially expansive element, the cutting surface positioned a distance radially outwardly from the radially expansive element, as seen in figure 1b and discussed above. The recitation "so that the cutting surface traverses the inner layer to the outer layer without penetrating the outer layer upon expansion of the element" is considered function language and does not hold patentable weight in an apparatus claim. Further the device of Lemelson is capable of performing the function to some degree depending on the amount of inflation and the vessel size.

Regarding claim 2, Lemelson discloses that as applied to claim 1. Further, the device is positioned within a blood vessel and the cutting surface is positioned a distance radially outwardly from the radially expansive element. The device is capable of traversing the intimal layer to the adventitial layer without penetrating the adventitial layer upon expansion of the element, as discussed above.

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Regarding claim 5, Lemelson et al. disclose that as applied to claim 2, as well as, a dissection tool that includes a mechanism that rotates cutting surface, as recited in column 4, lines 1-20.

Regarding claim 8, Lemelson et al. disclose that as applied to claim 2, as well as, a dissection tool includes a mechanism that advances the radially expansive element. Further, the phrase, "*along a portion of the adventitial layer to delaminate the intimal layer from the adventitial layer along a segment of the blood vessel*" is considered function language. However, the apparatus of Lemelson is capable of performing the function.

Regarding claim 10, Lemelson et al. disclose that as applied to claim 2, as well as, a dissection tool that includes an inflatable member (11) surrounded by the radially expansive element so that the element is expandable by action of the inflatable member, as recited in column 4, lines 1-20.

Regarding claim 73 (renumbered 97), Lemelson et al. disclose that as applied to claim 1, as well as, a catheter body that includes a guidewire (12) lumen extending between the proximal and distal ends, as seen in figures 1a-3.

5. Claims 48 and 71 (renumbered 95) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lemelson et al. in US Patent No. 5,728,123.

Regarding claim 48, Lemelson et al. disclose a device having a catheter body (9) having a proximal end, a distal end, and a lumen therethrough; and a dissection mean (18) disposed near the distal end of the catheter body, as recited in column 2, lines 35-40, column 2, lines 60-65, columns 3 and 4 and seen in figures 1A-1B, for example. The phrase, "*for traversing the inner layer to the outer layer without penetrating the outer layer to expose a portion of the outer layer*" is considered function language and does not hold patentable weight in an apparatus claim. Further the device of Lemelson is capable of performing the function to some degree and will depend on vessel size and amount of inflation. Further, if this claim is intended to be a 112 6th paragraph means plus function recitation, then the structures can be considered obvious equivalents.

Regarding claim 71 (renumbered 95), Lemelson et al. disclose that as applied to claim 1. Further, column 5, lines 25-35 discuss the use of aspiration/section to remove debris. Thus, an aspiration pump in the catheter body would be necessary if not inherent for proper function.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 5,697,944.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700

